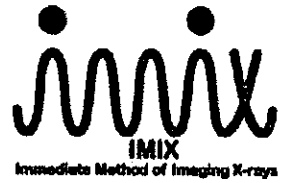
510(k) Summary K101435



K101435

SEP 15 2010

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Contact: Sigrid Smitt-Jeppesen President and CEO IMIX Americas
Date Prepared: May 13, 2010

1. Identification of the Device:
   Proprietary-Trade Name: IMIX PanoRad and SomaRad X-Ray Systems
   Classification Name: Stationary X-ray system,
   Product Codes Product Codes KPR, MQB, and LLZ
   Common/Usual Name: General purpose diagnostic X-ray Unit.

2. Equivalent legally marketed devices: K073114, IMIX Insight; K083645 Radstar Digital Imaging System made by 5-Star, and K070618, DICOM Pacs made by O&R. The IMIX PanoRad and SomaRad X-Ray Systems use the identical panel to K083645 and the identical software to K070618.

3. Indications for Use (intended use) IMIX PanoRad and SomaRad X-Ray Systems are indicated for use in generating radiographic images of human anatomy. It has a Solid State X-ray Imaging system intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures. Not for mammography.

4. Description of the Device:
   The PanoRad consists of:
   - A high resolution CCD detector with 14" x 17" or 17" x 17" image area.
   - An X-Ray Tube & Collimator.
   - A fully motorized positioned
   - A 65 kW high frequency generator
   - A 4 way floating table
   - An Image Acquisition workstation with DICOM 3 compliance.

   The SomaRad consists of:
   - A high resolution CCD detector with 14" x 17" or 17" x 17" image area.
   - An X-Ray Tube & Collimator.
   - A fully motorized positioned
   - A 50 kW high frequency generator
   - A table
   - An Image Acquisition workstation with DICOM 3 compliance.

5. Safety and Effectiveness, comparison to predicate device. The results of bench, user, and standards testing indicates that the new device is as safe and effective as the predicate devices. The changed components are in fact identical to the predicate devices.

6. Substantial Equivalence Chart, IMIX PanoRad and SomaRad X-Ray Systems

Characteristic	**K073114, IMIX Insight**	**K083645 Radstar Digital Imaging System made by 5-Star**	**IMIX PanoRad and SomaRad X-Ray Systems, Combines cleared devices**
Intended Use:	General purpose diagnostic X-ray unit	Acquisition of x-ray images when incorporated into an x-ray system, a film substitute.	SAME
User Interface	Software Driven Touch Panel LCD	Windows computer	Software Driven Touch Panel LCD
Generator	Stadler	Not supplied	CPI or Stadler
Maximum output	40, 50, and 65 kW	Not supplied	50 and 65 kW
Stand	Supplied by Sedecal	Not supplied	Supplied by Shinyoung For M Co Ltd
Image Acquisition	Digital: IMIX Digital Radiographic Detector K974863	Varian	IMIX or Varian Digital Radiographic Detectors, 9 or 16 mp.
Digital Panel Size	Active image size: 16 x 16 inches (40cm x 40cm)	17" x 17", 14" x 17", 12" x 16" and 8" x 10" panel	14" x 17" (4336R) OR 17" x 17: (4343R)
Digital Panel Supplier	IMIX	Varian 4336 and others. (not specified)	Original IMIX panels, same as in K073114 **OR:** Varian 4343R OR 4336R
Digital Resolution	160 Micron. 3056 x 3056 (9 megapixels) or 120 Micron 4096 x 4096 (16 megapixels)	7.9 megapixel or 9.4 megapixel. 139 micron.	Same as original 510(k), 16 megapixels OR 7.9 megapixel or 9.4 megapixel. 139 micron.
DICOM	Yes	Optional	Yes, via O&R software cleared in K091364
Method of Control	Touch Panel LCD	Windows computer	Touch Panel LCD
Collimator	Ralco R302L/A DHHS	Not supplied	Ralco R302L/A DHHS
Safety	UL listed	UL listed	UL listed

7. Conclusion: After analyzing bench, user (clinical image pairs), and standards testing data, it is the conclusion of IMIX ADR that the IMIX PanoRad and SomaRad X-Ray Systems are as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

IMIX ADR Finland OY
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
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SEP 15 2010

Re: K101435
Trade/Device Name: IMIX PanoRad and SomaRad X-Ray Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: July 32, 2010
Received: July 29, 2010

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101435

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K101435